KNATURE CORPORATION

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street SW Washington, DC 20204



September 7, 1999

Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of Knature Corporation, who is, among other things, a manufacturer and distributor of dietary supplements, mostly herbal products in the United States. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

Knature Corporation

555 108th Ave NE, Suite 4 Bellevue, WA 98004

975 - 0162

LET 4400

Tel: (425) 646-5125 Fax: (425) 646-5098

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Marital Bliss for Women

The common and usual name of the product:

None.

A label copy showing all information displayed and provided to consumers is attached.

4. The text of the Structure/Function Statement:

Herbal Supplement for female well-being.

Marital Bliss for women is a botanical blend of Chinese herbs formulated to maintain a healthy womanhood, especially in promoting female well-being.

5. Ingredient Statement

This product is a proprietary blend of botanicals. The following is a complete list of dietary ingredients:

Common Name	Chinese Name	Latin Binomial	Part of Plant
White Atractilodes	Bai Zhu	Atractylodes macrocephala Koi	dz Root
Chinese Angelica	Dong Quai	Angelica sinensis (Olive) Diels	
White Peony	Bai Shao	Paeonian lactiflora Pall.	Root
Salvia	Dan Shen	Salvia miltiorrhiza Bunge	Root
Rehmannia, prepared	Shu Di Huang	Rehmannia glutinosa Libosch	Root
Gentian	Qin Jiao	Gentiana macrophylla Fisch	Root
Ligusticum Wallichii	Chuanxiong	Ligusicum chuanxiong Hort.	Root
Chinese Licorice	Gan Cao	Glycyrrhiza uralensis Fisch.	Root
Motherwort	Yi Mu Cao	Leonurus heterophyclus Sweet	Branch & Lea

6. Intended Use:

This product is intended to be used by adult female over the age of 16.

Dosage: 10 capsules (10 x 750 mg) each time, twice daily.

Warning: Not recommended for male of any age, or female under the age of 16. Do not take this herbal capsule during menstrual period, nor if you are pregnant or lactating. Consult your physician if you are on any type of medication. Should you have any questions regarding the use of this product, please consult your doctor or call the product hot line in U.S. at 425-646-5125. Keep out of reach of children.

7. Statement of Affirmation:

We, as a manufacturer and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to another statement called disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement. The disclaimer reads:

The statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above, or contact the preparer of this letter:

George Su, Ph.D. Crosslinks International, Inc. 1800 Century Park East, Suite 600 Century City, CA 90067

Tel: (310) 229-5748
Fax: (419) 715-4365
E-Mail: crosslinks@aol.com

Sincerely,

Dongning Wen
Dongning Wen
President

Enclosure

KNATURE

For Women Marital Bliss

Herbal Supplement

For female well-being*

Chinese traditional formula! 300 years old

(750 mg each) 120 Capsules

> of the herbs' synergism of the Chinese healing arts upon the ancient principles Knature's Marital Bliss for accordance when combined Women is formulated based bioenergetic properties. It takes the best advantages with

Marital Bliss for Women is promoting female wellwomanhood, especially in to maintain a healthy Chinese herbs formulated botanical blend of

maximum purity, potency carefully selected to insure Extracts." The herbs in this formula extraction procedures are set forth in the Chinese to the stringent standards tested before use according and freshness. maintain the herbs' ful classic Chinese method to Pharmacopoeia. spectrum of all ingredients strictly following They are They are Spectrum

Supplement Facts

corn, wheat, soy or milk artificial added. No preservatives; no No sugar, salt, starch, yeast, flavorings colors;

Food not been evaluated by the * These statements have product is not intended to Administration. prevent any disease diagnose, treat, cure, or and Drug

> mg) each time, twice daily. Directions: 10 capsules (10 x 750

Warning:

of 16. Do not take this herbal any age, or female under the age Not recommended for male of capsule during menstrual period, if you are on any type of nor if you are pregnant or out of reach of children. this product, please consult your questions regarding the use of medication. Should you have any lactating. Consult your physician in U.S. at 425-646-5125. Keep doctor or call the product hot line

Bellevue, WA 98004 **Knature Corporation** Imported and Distributed by: Tel: (425)646-5125

Product of China

Expiration Date:

Facts Supplement Serving Size: 10 capsules (7500 mg) Servings Per Bottle 12 % Daily Value* Amount per Serving Calories 10 Total Carbohydrates 2 g Proprietary blend 4.5 g White Atractilodes (root) Chinese Angelica (root) White Peony (root) Saliva (root) Rehmannia, Prepared (root) Gentian (root) Ligusticum Wallichii (root) Chinese Licorice (root) Motherwort (branch & leaf) Not a significant source of other nutrients. * Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.

Label No.: 6081702

Client No.: K06

Product: Marital Bliss for Women

 $(120 \times 750 \text{ mg})$